

CONSIDER THE COMPARATIVE EFFICACY OF DALMANE® VS. (flurazepam HCl/Roche) OTHER SLEEP MEDICATIONS



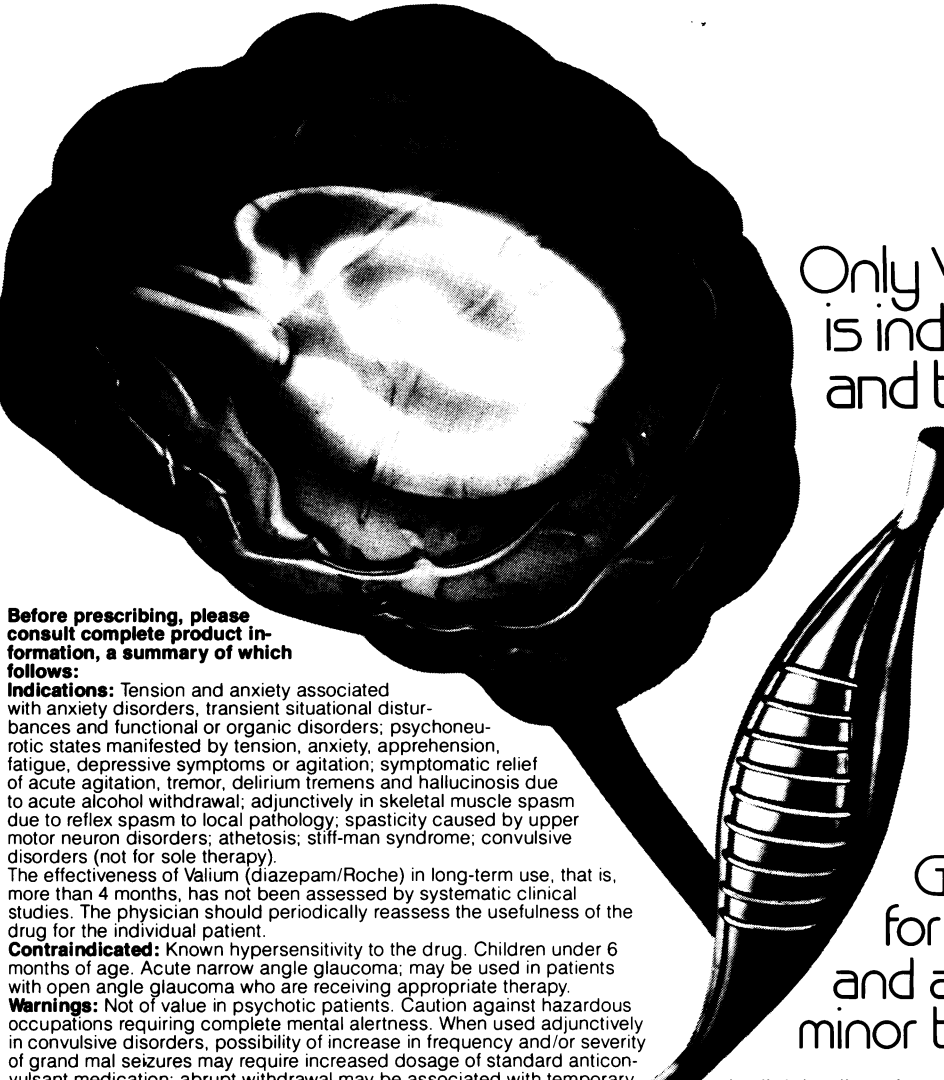
Sleep research laboratory studies show Dalmane (flurazepam HCl/Roche) more effective for more nights than other sleep medications tested

Polygraphic appraisal of sleep in 36 insomniac subjects over 14 consecutive nights, proved that of the 9 medications* tested, only Dalmane

remained significantly effective for the duration of the study.¹

While it is reassuring that efficacy can be maintained for this period of time if needed, pharmacological treatment of insomnia should be initiated with the lowest possible effective dose and continued only as long as judged appropriate to achieve a therapeutic goal.

*The drugs studied included 7 commercially available and 2 investigational hypnotics.



Only Valium® (diazepam/Roche)
is indicated in anxiety
and tension states
and as an
adjunct in the
relief of skeletal
muscle spasm

Before prescribing, please consult complete product information, a summary of which follows:

Indications: Tension and anxiety associated with anxiety disorders, transient situational disturbances and functional or organic disorders; psychoneurotic states manifested by tension, anxiety, apprehension, fatigue, depressive symptoms or agitation; symptomatic relief of acute agitation, tremor, delirium tremens and hallucinosis due to acute alcohol withdrawal; adjunctively in skeletal muscle spasm due to reflex spasm to local pathology; spasticity caused by upper motor neuron disorders; athetosis; stiff-man syndrome; convulsive disorders (not for sole therapy).

The effectiveness of Valium (diazepam/Roche) in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.

Contraindicated: Known hypersensitivity to the drug. Children under 6 months of age. Acute narrow angle glaucoma; may be used in patients with open angle glaucoma who are receiving appropriate therapy.

Warnings: Not of value in psychotic patients. Caution against hazardous occupations requiring complete mental alertness. When used adjunctively in convulsive disorders, possibility of increase in frequency and/or severity of grand mal seizures may require increased dosage of standard anticonvulsant medication; abrupt withdrawal may be associated with temporary increase in frequency and/or severity of seizures. Advise against simultaneous ingestion of alcohol and other CNS depressants. Withdrawal symptoms similar to those with barbiturates and alcohol have been observed with abrupt discontinuation, usually limited to extended use and excessive doses. Infrequently, milder withdrawal symptoms have been reported following abrupt discontinuation of benzodiazepines after continuous use, generally at higher therapeutic levels, for at least several months. After extended therapy, gradually taper dosage. Keep addiction-prone individuals under careful surveillance because of their predisposition to habituation and dependence.

Usage in Pregnancy: Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Precautions: If combined with other psychotropics or anticonvulsants, consider carefully pharmacology of agents employed; drugs such as phenothiazines, narcotics, barbiturates, MAO inhibitors and other antidepressants may potentiate its action. Usual precautions indicated in patients severely depressed, or with latent depression, or with suicidal tendencies. Observe usual precautions in impaired renal or hepatic function. Limit dosage to smallest effective amount in elderly and debilitated to preclude ataxia or oversedation.

Side Effects: Drowsiness, confusion, diplopia, hypotension, changes in libido, nausea, fatigue, depression, dysarthria, jaundice, skin rash, ataxia, constipation, headache, incontinence, changes in salivation, slurred speech, tremor, vertigo, urinary retention, blurred vision. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances, stimulation have been reported; should these occur, discontinue drug. Isolated reports of neutropenia, jaundice; periodic blood counts and liver function tests advisable during long-term therapy.

Dosage: Individualize for maximum beneficial effect. **Adults:** Tension, anxiety and psychoneurotic states, 2 to 10 mg b.i.d. to q.i.d.; alcoholism, 10 mg t.i.d. or q.i.d. in first 24 hours, then 5 mg t.i.d. or q.i.d. as needed; adjunctively in skeletal muscle spasm, 2 to 10 mg t.i.d. or q.i.d.; adjunctively in convulsive disorders, 2 to 10 mg b.i.d. to q.i.d. **Geriatric or debilitated patients:** 2 to 2½ mg, 1 or 2 times daily initially, increasing as needed and tolerated. (See Precautions.) **Children:** 1 to 2½ mg t.i.d. or q.i.d. initially, increasing as needed and tolerated (not for use under 6 months).

Supplied: Valium® Tablets, 2 mg, 5 mg and 10 mg—bottles of 100 and 500; Tel-E-Dose® packages of 100, available in trays of 4 reverse-numbered boxes of 25, and in boxes containing 10 strips of 10; Prescription Paks of 50, available in trays of 10.

General guidelines
for the prescribing
and appropriate use of
minor tranquilizers

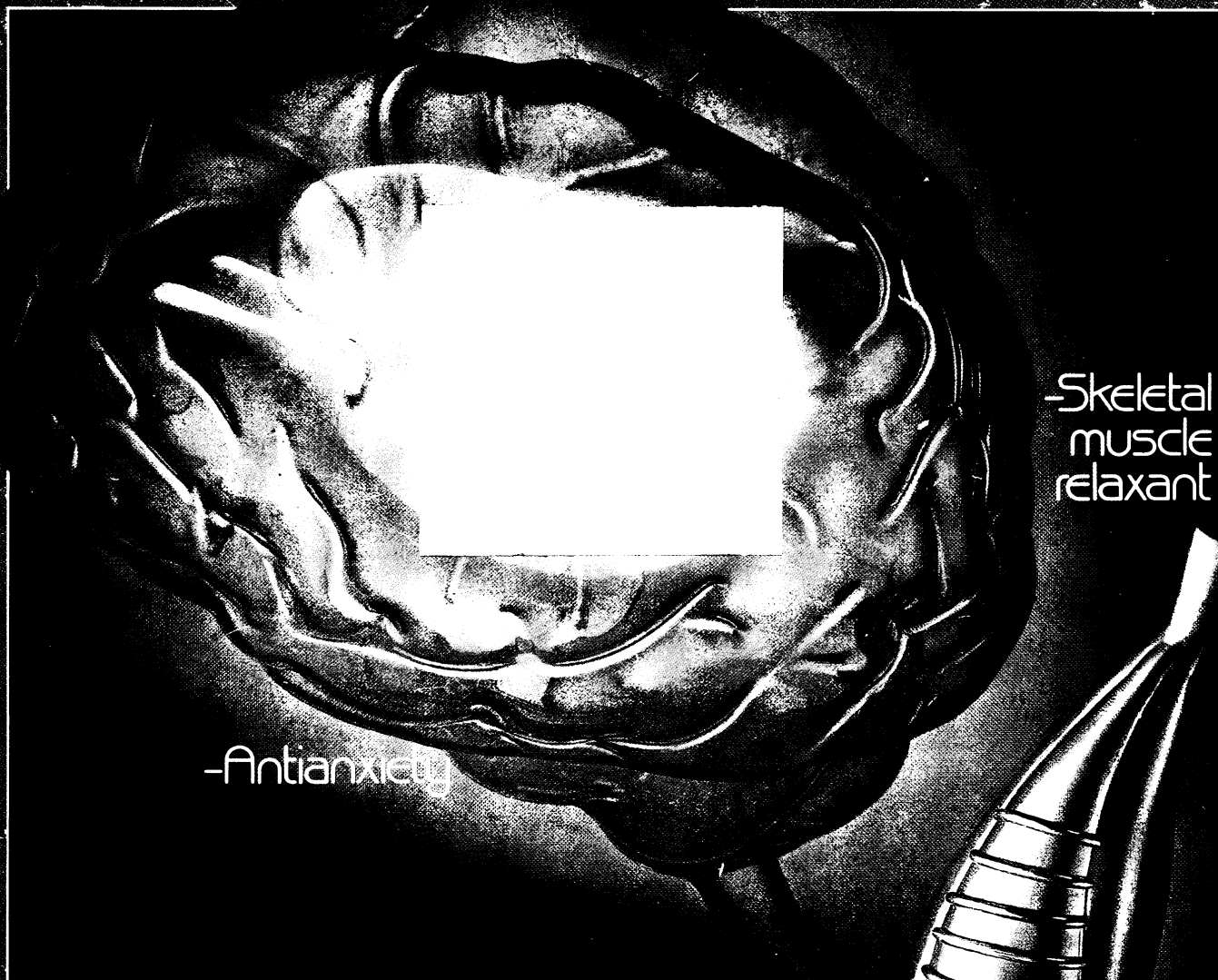
- Individualize dosage for maximal beneficial effect.
- Prescribe the specific quantity needed until the next checkup period, schedule frequent, periodic reexaminations to monitor results of therapy.
- Establish treatment goals and gradually discontinue medication when these have been met.
- Avoid prescribing for individuals who appear dependency-prone or whose histories indicate the potential for misuse of psychoactive substances, including alcohol.
- Caution patients against engaging in hazardous occupations requiring complete mental alertness such as operating machinery or driving.
- Advise patients against the ingestion of alcoholic beverages while undergoing therapy with minor tranquilizers.
- Counsel patients to follow label directions, keep medication out of children's reach, and dispose of unused or old medication.
- Caution patients against giving medication to others.
- Avoid abrupt cessation of extended therapy by tapering dosage before discontinuing medication.



Roche Laboratories
Division of Hoffmann-La Roche Inc.
Nutley, New Jersey 07110

Only Valium® (diazepam/Roche)
has these two distinct effects

mind & muscle



-Skeletal
muscle
relaxant

-Antianxiety

2-mg, 5-mg, 10-mg
• scored tablets
Valium®
diazepam/Roche

Indicated in anxiety and tension
states and as an adjunct in the
relief of skeletal muscle spasm

Please see summary of
product information
on preceding page.

